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*AP 1615*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION

OF: WITTELER ET AL.

SERIAL NO. 10/070,758

FILED: MARCH 12, 2002

FOR: PROCESS FOR PREPARING POLYVINYLPIRROLIDONE-IODINE IN AQUEOUS SOLUTION

BOX: AF

CONFIRMATION NO.: 2769

GROUP ART UNIT: 1615

EXAMINER:

BLESSING M. FUBARA

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REPLY UNDER 37 C.F.R. §1.113(c) AND §1.116

Sir:

In reply to the Office action of February 13, 2004, it is respectfully requested that the following request for reconsideration be entered and considered by the Examiner:

REQUEST FOR RECONSIDERATION

Claims 1 to 9 and 12 as submitted by applicants in Paper No. 07, dated October 31, 2003, are currently pending.

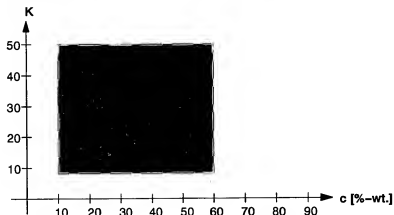
Claims 1 to 9 and 12 stand finally rejected under 35 U.S.C. §102(b) as being anticipated by the disclosure of *Denzinger et al.* in *US 4,402,937* which relates to the preparation of PVP-iodine in aqueous solution. As pointed out by the Examiner, *Denzinger et al.* disclose that

- the PVPs employed in the process have a K value of from 8 to 50<sup>1)</sup>; and

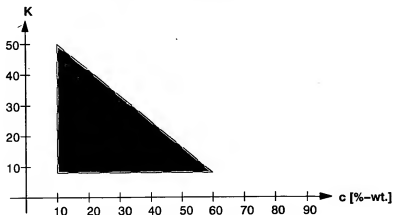
1) See col. 3, indicated lines 37 to 41, of *US 4,402,937*.

- the aqueous PVP solutions have a PVP concentration of from 10 to 60%<sup>2)</sup>.

Based on the respective information referenced by the Examiner, the range of K values and concentrations would correspond to the shaded area in the following graphical representation:



However, **Denzinger et al.** further state "the higher concentrations applying to polymers of low K value, and vice versa"<sup>3)</sup>. Accordingly, **Denzinger et al.** do not teach that any and all combinations of K values and concentrations within the shaded area of the above representation are useful. Rather, in accordance with **Denzinger et al.**, the high concentration of 60% by weight applies to the PVP having the low K value of 8, and the low concentration of 10% by weight applies to the PVP having the high K value of 50. In accordance with the teaching of **Denzinger et al.** the area of useful combinations of K values and concentration§ lies therefore not within the foregoing square but within the following triangle:



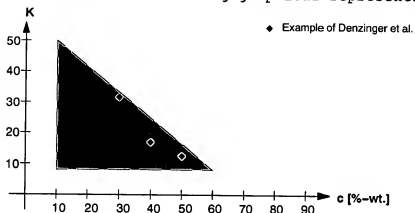
2) See col. 4, indicated lines 33 to 35, of **US 4,402,937**.

3) See col. 4, indicated lines 35 to 37, of **US 4,402,937**.

Corresponding to the area of useful combinations of K values and PVP concentrations represented by the foregoing triangle, *Denzinger et al.* illustrate their process using<sup>4)</sup>

- a 30% by weight aqueous solution of a PVP having a K value of 31.5 in Example 1;
- a 40% by weight aqueous solution of a PVP having a K value of 16.5 or 17 in Examples 2, 4 and 5a to 5c; and
- a 50% by weight aqueous solution of a PVP having a K value of 12.5 in Example 3,

which are illustrated in the following graphical representation:



The Examiner's evaluation of the scope and content of *Denzinger et al.*'s disclosure disregards *Denzinger et al.*'s statement correlating high concentrations with low K values and vice versa. The Examiner's conclusion that applicants' invention is anticipated by *Denzinger et al.*'s teaching is therefore deemed to be in error<sup>5)</sup>.

Applicants' invention is drawn to a process for preparing PVP-iodine which inter alia requires that an aqueous PVP solution is employed which has a PVP concentration c which is larger than the value resulting from the calculation  $100 \times [0.1 + 8 : (K + 5)]$ . As already submitted by applicants, anticipation requires that the identical invention is shown in the reference in as complete detail as is contained

4) See the more detailed remarks in applicants' Paper No. 07, dated October 31, 2003, on pages 3 to 4.

5) It is impermissible within the framework of Section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art (*In re Hessler*, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965); *In re Mercer*, 515 F.2d 1161, 185 USPQ 774, (CCPA 1975); *Bausch & Lomb v. Barnes-Hind/Hydrocurve*, 796 F.2d 443, 230 USPQ 416 (CAFC 1986)). Anticipation is the ultimate or epitome of obviousness (*In re Grosse*, 592 F.2d 1161, 201 USPQ 57 (CCPA 1979)).

in the claim<sup>6</sup>). Accordingly, to anticipate applicants' process within the provisions of Section 102(b), the teaching of *Denzinger et al.* has to show the utilization of an aqueous PVP solution meeting the requirement

$$C > 100 \times [0.1 + 8 : (K + 5)]$$

of applicants' claims.

The solution which is employed by *Denzinger et al.* in Example 1 contains a PVP having a K value of 31.5 and having a PVP concentration of 30% by weight. If the K value of 31.5 is entered in applicants' formula, the following results

$$\begin{aligned} C_{31.5} &> 100 \times [0.1 + 8 : (31.5 + 5)] \\ &> 100 \times [0.1 + 8 : 36.5] \\ &> 100 \times [0.1 + 0.219] \\ &> 100 \times [0.319] \\ &> \underline{31.9} \end{aligned}$$

The solution which is shown by *Denzinger et al.* in Example 1 only has a PVP concentration of 30% by weight. Example 1 of *Denzinger et al.* therefore fails to identically show applicants' process as defined in the claims.

Correspondingly: in Examples 2 and 5a to 5c *Denzinger et al.* employ PVP having a K value of 16.6 in a concentration of 40% by weight. Entering the K value of 16.6 into applicants' formula, the following results:

$$\begin{aligned} C_{16.6} &> 100 \times [0.1 + 8 : (16.6 + 5)] \\ &> \underline{47} \end{aligned}$$

The solution which is shown by *Denzinger et al.* in Examples 2 and 5a to 5c only has a PVP concentration of 40% by weight. Examples 2 and 5a to 5c of *Denzinger et al.* therefore also fail to identically show applicants' process as defined in the claims.

Correspondingly: in Example 3 *Denzinger et al.* employ PVP having a K value of 12.5 in a concentration of 50% by weight. Entering the K value of 12.5 into applicants' formula, the following results:

$$\begin{aligned} C_{12.5} &> 100 \times [0.1 + 8 : (12.5 + 5)] \\ &> \underline{55.7} \end{aligned}$$

The solution which is shown by *Denzinger et al.* in Example 3 only has a PVP concentration of 50% by weight. Example 3 of *Denzinger et al.*

6) *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (CAFC 1989)

therefore also fails to identically show applicants' process as defined in the claims.

Correspondingly: in Example 4 *Denzinger et al.* employ PVP having a K value of 17 in a concentration of 40% by weight. Entering the K value of 17 into applicants' formula, the following results:

$$C_{17} > 100 \times [0.1 + 8 : (17 + 5)] \\ > 46.4$$

The solution which is shown by *Denzinger et al.* in Example 4 only has a PVP concentration of 40% by weight. Example 4 of *Denzinger et al.* therefore also fails to identically show applicants' process as defined in the claims.

The teaching of *Denzinger et al.* otherwise does not disclose or show a particular correlation of one K value to one concentration which is sufficiently specific to meet the requirements for an anticipating disclosure. The ranges of K values and concentrations which are mentioned by *Denzinger et al.* and which were addressed at the outset lack the specificity which is necessary for an anticipating disclosure within the provisions of Section 102. It is well settled that a genus lacks the specificity to anticipate a species which falls within its realm<sup>7)</sup>. Correspondingly, it is well settled that a range provided in the prior art does not per se anticipate a claimed range which touches, overlaps or is within the prior art range where -as here- no specific examples falling within the claimed range are disclosed in the prior art<sup>8)</sup>. In light of the foregoing and applicants' previous presentations, the teaching of *Denzinger et al.* clearly fails to provide for a disclosure which anticipates the invention defined by applicants' claims within the meaning of Section 102(b), and the Examiner's rejection should therefore be withdrawn. Favorable action is solicited.

In light of the Examiner's response to applicants' previous arguments the following clarifications are respectfully submitted.

The Examiner takes the position that applicants cannot argue with reference to the viscosity of the aqueous PVP solution because the viscosity is not recited in the claims. The viscosity of the aqueous PVP solution is inherent in the concentration of the solution and

7) For example, *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (CAFC 1992).

8) For example, *Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2f 1559, 24 USPQ2d 1321 (CAFC 1992).

applicants' claims clearly define the requisite PVP concentration. As explained by applicants in their previous paper an increase in concentration results in an increase in the viscosity of the solution. While neither applicants' claims nor, for that matter, the teaching of *Denzinger et al.*, specifically address viscosity, the correlation between viscosity of the aqueous PVP solution and the PVP concentration is well known in the art. Moreover, the respective correlation as well as the correlation between viscosity of the aqueous PVP solution and the K value of the PVP employed explains *Denzinger et al.*'s statement that the high concentrations are applicable for solutions of PVPs having a low K value and vice versa. Applicants' reference to the viscosity of the aqueous PVP solution therefore does not require that a viscosity limitation is read into applicants' claims as the Examiner would have it. The viscosity limitation is inherent in applicants' formula  $c > 100 \times [0.1 + 8 : (K + 5)]$ .

The Examiner's criticism that applicants' claims fail to recite a specific concentration is not deemed to be well taken. In accordance with applicants' invention it is required that the PVP concentration in the aqueous solution be adapted in a particular manner, as defined in applicants' formula  $c > 100 \times [0.1 + 8 : (K + 5)]$ , depending on the K value of the PVP which is employed. The respective aspect of applicants' invention clearly cannot be expressed by recitation of a specific concentration or by reference to a concentration range.

The Examiner's position that the table set forth on page 4 of the previous reply does not exclude other combinations which are possible within the range generically provided for in *Denzinger et al.*'s disclosure is not deemed to be pertinent to the question of anticipation. The mere fact that combinations beyond the exemplified combinations are possible is insufficient to show anticipation. "[A]lthough specific claims are subsumed in [a prior art reference's] generalized disclosure ... this is not identity"<sup>9)</sup> and anticipation requires that the identical invention is shown in one prior art reference<sup>10)</sup>.

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9) Id. fn. (8), 24 USPQ2d at 1332.

10) *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771, 218 USPQ 781, 789 (CAFC 1983), cert. denied, 465 U.S. 1026 [224 USPQ 520] (1984), overruled-in-part on other grounds, *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1125, 227 USPQ 577, 588-89 (CAFC 1985) (en banc)

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WITTELER et al.

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Respectfully submitted,

KEIL & WEINKAUF



Herbert B. Keil

Reg. No. 18,967

1350 Connecticut Ave, N.W.  
Washington, D.C. 20036  
(202) 659-0100

HBK/BAS